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Mr. Steven B. Barber  
Compliance Officer  
Baltimore District Office  
United States Food and Drug Administration  
6000 Metro Drive (Suite 101)  
Baltimore, MD 21215-3215

11 October, 2005

**Re: Warning Letter – Panbio Inc. September 20, 2005**

Dear Mr. Barber,

This letter is a response to the Warning Letter issued by the Food and Drug Administration on September 20, 2005 and received September 21, 2005 by Panbio Inc. Panbio acknowledges receipt of a revised Warning Letter issued by the FDA on October 5th, 2005 omitting the reference to 'the FDA-483 issued at the close of inspection' that was not received. Panbio is deeply concerned about the issues raised in this Warning Letter. Panbio has always sought to operate within the scope of the law and the FDA's implementing regulations and guidance. However, Panbio does not agree with the Warning Letter assertion that Panbio has offered uncleared/unapproved products for sale in the United States.

**Regarding the sale of Human Herpesvirus 6 IgM and IgG IFA kits in the United States:**

Please be assured that Panbio does not sell Human Herpesvirus 6 IgM and IgG IFA kits in the United States. Neither Panbio's United States catalogue nor its United States web page list Human Herpesvirus 6 IgM and IgG IFA kits for sale in the United States.

With respect to the availability of the Australian catalogue and Australian product inserts, Panbio acknowledges that the Australian catalogue, as well as the product inserts, is accessible to United States customers through our international web pages. However, it is Panbio's position that the availability of product information regarding test kits or other products on its international web pages should not be construed to be United States promotional material, where

- a) the availability of this information is not being used to promote products in the United States and

- b) the United States and international web sites are clearly differentiated.

Indeed, it is our understanding that this position is consistent with well-established practices in the drug/biologic/medical device industries. However, to assure that only products or uses that conform to United States requirements are promoted and marketed to Panbio's United States customers, Panbio is reviewing its corporate website and the company's Australian, International and United States catalogues to confirm that:

- a) Only labeling consistent with United States regulatory requirements is used with products sold or marketed in the United States and
- b) Products identified on our international web pages that are not available in the United States clearly reflect this fact.

In this regard, all product inserts identified on the International and Australian pages of the website for products not available for sale or distribution in the United States also now clearly state this fact. Please refer to Panbio's website to confirm this change.

With respect to the sale of unapproved/uncleared test kits to United States customers: No United States customers can obtain the subject products by placing an order through the Australian or the International web pages. It is the case that Panbio received orders for the subject products from one licensed high complexity clinical laboratory. However, Panbio did not supply any test kits to this customer. Panbio supplied components without any labeling, instructions for use or performance information. Sales of the components to this customer are reflected in the documents that the Agency Inspectors collected during the May inspection.

Nevertheless, in view of the Warning Letter, Panbio has modified its procedure for responding to orders for test kits that are not available for sale in the United States. This modified procedure requires that the order be returned to the ordering customer with the advice that the subject kit is not available for sale to customers in the United States.

## **Regarding ELISA ASRs and IFA Slides**

With respect to Panbio products listed as ELISA ASRs, it is Panbio's position that because the ELISA ASRs were not supplied with labeling, product inserts or performance information they meet the definition of ASRs as set forth in 21 CFR Sec.864.4020 and are not "capable of functioning" according to the definition of a finished device (21 CFR Sec.820(l)) except when they are utilized as a component of a diagnostic test manufactured by a licensed high complexity clinical laboratory or an *in vitro* diagnostic device manufacturer.

Regarding the claim that "products described on [Panbio's] website as IFA components, specifically the HHV6 IFA Slides, may be finished devices rather than components of devices", Panbio assures the Agency these are components as defined in 21 CFR 820.3(c) and only intended for sale as ASRs. IFA components are "not capable of functioning" except when they

are utilized as a component of a diagnostic test manufactured by a licensed high complexity clinical laboratory or an *in vitro* diagnostic device manufacturer.

The Warning Letter has brought to Panbio's attention the inclusion of inappropriate material contained on component web pages, including the HHV6 IFA Slides page. The inclusion of this information was unintentional and was due to an unperceived link between Panbio's Australian, International and United States pages that allowed material destined solely for non-United States web pages to be added to the United States page inadvertently. Upon discovering this situation, Panbio removed all inappropriate material from its website. To assure that this situation does not recur, the United States web page has been made independent of the International and Australian web pages. Any further updates to these latter pages will not be reflected in the United States web page. Panbio has also established a procedure for the review of all United States web page materials to assure that these materials meet the requirements of United States law and regulations.

Panbio is committed to operating within the scope of the law and the Agency's implementing regulations and published guidance. During the inspection, the representative of the Office of *In Vitro* Diagnostic Device Evaluation and Safety advised Panbio that the Agency might have issues pertaining to Panbio marketing practices that reflected new regulatory policies that the Agency was considering. Understanding this, Panbio requests the opportunity to meet with Office of *In Vitro* Diagnostic Device Evaluation and Safety personnel to discuss and to further understand these new policies and to present Panbio's views.

Panbio requests this response letter be published on the FDA website.

Sincerely yours,



Carl Stubbings  
Senior Vice President

CC; Donald J. St. Pierre  
Kathleen B. Whitaker Ph.D.  
Thomas O. Henteleff  
Anthony L. Young

OIVD  
OIVD  
Counsel for Panbio Inc.  
Counsel for Panbio Inc.